EXHIBIT D

MINUTES

UTAH PHYSICIAN'S BOARD MEETING

July 9, 2008

Room 474 – 4th Floor – 9:00 A.M. Heber Wells Building Salt Lake City, UT 84111

CONVENED: 9:13 A.M. ADJOURNED: 2:15 P.M.

Bureau Manager:Nocl TaxinBoard Secretary:Karen McCallDivision Compliance Specialist:Debbie Harry

Board Members Present: Marc E. Babitz, MD, Board Chairperson

James R. Fowler, MD John W. Bennion, Ph.D. Kristen Ries, MD Richard J. Sperry, MD

Lori G. Buhler

George C. Pingree, MD Stephen E. Lamb, MD James H. Pingree, MD Elizabeth F. Howell, MD

Board Members Absent: Vacant Position

Guests: Larry Keller

Doug McClain, Argyll Biotech

DOPL Staff Present: David Stanley, Division Director

Diane Hooper, Licensing Specialist Kent Barnes, Sr. Business Analyst Ronda Trujillo, Compliance Specialist

<u>TOPICS FOR DISCUSSION</u> <u>DECISIONS AND RECOMMENDATIONS</u>

ADMINISTRATIVE BUSINESS:

MINUTES: The minutes from the June 4, 2008 Board meeting

were read.

Dr. George Pingree made a motion to approve the

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minutes with minor revisions. Dr. Howell seconded the motion. The Board vote was unanimous.

APPOINTMENTS:

9:45 am

Debbie Harry, Compliance Update

Ms. Harry updated the Board regarding the compliance or non-compliance of probationers.

Ms. Harry reported that **Dr. David L. Aune** is currently in compliance.

Ms. Taxin reminded the Board that Dr. Aune's Order should be amended and reflect in the minutes that he has completed the aftercare requirement.

The Board acknowledged that Dr. Aune has successfully completed the aftercare requirement.

Ms. Harry reported that **Dr. William R. Gulledge** is currently out of compliance as his information from Texas has not been received.

Ms. Taxin stated that one report from Texas was received but the report due for this meeting has not been received.

Ms. Harry reported that **Dr. Jason Church** will be in compliance if he brings in copies of his Controlled Substance prescriptions.

Ms. Harry reported that **Dr. Randall N. Ellsworth** is currently out of compliance as he has not submitted the PIR information, the 12-step attendance cards or the therapy report. She stated that he also has missed calling twice for his drug tests. Ms. Harry stated that the supervisor report was received but the employer report has not been received since October 2007.

Ms. Harry reported that **Dr. Brandon G. Bentz** is currently in compliance. She stated that Dr. Bentz's therapist recommended his therapy be terminated and would support reduction in Dr. Bentz probation period. She stated that Dr. Bentz has had problems with insurance companies dropping him off their lists.

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Ms. Taxin stated that Dr. Bentz could meet again in September 2008 for the Board to consider termination of probation.

Dr. Babitz commented that Dr. Bentz has reported that the insurance carriers have not dropped him.

Ms. Harry responded that it might be the Veterans Administration that has dropped him.

The Board suggested they wait until after Dr. Bentz's appointment to make any recommendation regarding his probation.

Ms. Harry reported that **Dr. Michael Goates** is currently out of compliance as 18 out of 19 drug tests have been positive with several high levels. She stated that he is in compliance with his reports and paperwork.

Ms. Taxin commented that the Board could ask if he is drinking and listen to his response. She stated that she reminded the Board that she talked with Dr. Goates in a previous meeting and recommended that he stop using his mouthwash or get an alcohol free alternative and speak to his Dentist if that is what he needs to do to have negative drug tests. She stated that Dr. Goates has reported to his therapist that he not drinking.

Dr. Howell asked if there would be a different Order if there is a Hearing or if Dr. Goates would be held to the current Order. She stated that there have been times when the Board has requested more of the probationers than is required in their original Stipulation and Order.

Ms. Taxin responded that in a Hearing the Board listens to the facts and then makes recommendations such as revocation or making a change to the current Stipulation and Order. She recommended the Board think about the clauses they have reviewed in Stipulations and Orders when they are making recommendations after a Hearing.

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Ms. Buhler asked if Dr. Goates was required to refrain from drinking alcohol in his current Order.

Ms. Harry responded that the current Order requires Dr. Goates to abstain from use or possession of alcohol, any mood altering substances, controlled substances or Rx drugs unless prescribed by a Physician for a real, current illness and must be taken correctly. She stated that a copy of all prescriptions is to be submitted to the Division

Ms. Harry reported that **Dr. Stanton A. Bailey** is currently in compliance with his Stipulation and Order. She stated that he has had negative drug tests with one diluted test in 2004, has never missed a drug test and has consistently submitted all required paperwork. She stated that Dr. Bailey has continued to attend PIR and AA meetings. Ms. Harry stated that Dr. Bailey has submitted a request for early termination of his probation. She stated that July 20, 2009 is the date that Dr. Bailey's probation is scheduled to terminate.

Dr. James Pingree made a motion for Dr. Bailey to have another psychological evaluation and have the Psychologist submit a copy of the evaluation with a recommendation for the Board to consider early termination of probation. Dr. Howell seconded the motion. The Board vote was unanimous.

The Board recommended Dr. Bailey return to Dr. Crookston for the second evaluation.

10:00 am

Dr. Walter E. Brodis. Reinstatement of License Discussion

Dr. Brodis and his wife. Donna Brodis, met with the Board to discuss reinstating his license.

Board members and Division staff were introduced.

Dr. Bennion made a motion to close the meeting for the discussion as personal private information will be discussed. Dr. James Pingree seconded the motion. The Board vote was unanimous.

Dr. Sperry made a motion to reopen the meeting.

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Dr. Howell seconded the motion. The Board vote was unanimous.

Dr. Howell made a motion for Dr. Brodis to submit documentation of completing the following when he submits his application for reinstatement of his license:

- 1. Complete a training/residency program to update his skills.
- 2. Take and pass the SPEX examination.
- 3. Request Dr. Bushnell to write a letter regarding the issues Dr. Brodis is currently working on and make a recommendation regarding if Dr. Brodis is safe to practice.
- Complete a neuropsychiatric test and submit a report that also identifies any problems or concerns.
- 5. Complete 40 hours of current CE.
- Meet again with the Board after above has been completed and submitted.

Dr. Sperry seconded the motion. The Board vote was unanimous.

10:30 am

Dr. David Aune, Probationary Interview

Dr. Aune met for his probationary interview

Ms. Buhler conducted the interview.

Ms. Buhler informed Dr. Aune that he is in compliance with his Stipulation and Order. She asked Dr. Aune to briefly update the Board regarding what he is doing.

Dr. Aune responded that he is enjoying his work and has taken up the hobby of remote control helicopters.

Ms. Buhler stated that the Board acknowledges that information has been received from Dr. Crookston regarding Dr. Aune successfully completing his therapy program. She stated that the report documents that Dr. Aune is doing well. Ms. Buhler asked if he is attending PIR groups and AA meetings.

Dr. Aunc responded that he has been doing the 12 step

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program through the LDS church.

The Board discussed moving Dr. Aunc's appointment to twice a year with reports being due quarterly.

Ms. Buhler asked if Dr. Aune attended the University of Utah (U of U) week long drug school.

Dr. Aune responded that he did attend the U of U drug school.

Following additional discussion, Ms. Buhler made a motion to move Dr. Aune's appointments from quarterly to twice a year with reports to continue to be submitted quarterly and the prescription triplicates to be submitted quarterly.

Dr. George Pingree seconded the motion.

The Board vote was unanimous.

An appointment was made for Dr. Aunc to meet again in January 2009.

10:45 am Dr. William Gulledge, Telephonic Probationary Interview

Dr. Gulledge met for his telephonic probationary interview

Dr. Ries conducted the interview.

Dr. Ries informed Dr. Gulledge that a letter was received right after his last appointment with the Board but one has not yet been received for this quarter. She asked if he has contacted the Texas Board regarding submitting a letter for this quarter.

Dr. Gulledge responded that he has requested the Texas Board to send the letters quarterly and thought they would send them automatically. He stated he will contact them again. Dr. Gulledge commented that he has finished all his requirements. He stated that his probation in Texas was for a 1 year period and that ended about 2 weeks ago. He asked if Utah was going to release him from the Utah probation today.

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Ms. Taxin recommended Dr. Gulledge follow-up with Debbie Harry. She stated that for the Board to recommend termination of probation Dr. Gulledge would need to submit the following:

- 1. Documentation from Texas regarding successfully completing his probation and being terminated there.
- 2. A letter from him requesting early termination of the Utah probation.
- 3. Documentation of completing the CME course.
- 4. A letter from his therapist regarding the issues he has worked on, that a support system is in place and a recommendation supporting early termination of probation.

Dr. Gulledge interjected that he was not required by Texas to be in therapy.

Dr. Babitz asked if Dr. Gulledge had therapy in Texas.

Dr. Gulledge responded that he did.

Dr. Babitz, Dr. Ries and Ms. Taxin stated that it would be helpful for the Board when they consider termination of the Utah probation if he would have the therapist submit a letter.

The Board determined Dr. Gulledge is out of compliance with his Stipulation and Order until the paperwork is received.

An appointment was made for Dr. Gulledge to meet again September 10, 2008.

11:00 am

Dr. Jason Church, Probationary Interview

Dr. Church met for his probationary interview.

Dr. Howell conducted the interview.

Dr. Howell stated that Dr. Church's file is missing his copies of prescribed controlled substances (CS).

Dr. Church submitted the copies for the Board to

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review. He stated that he also found the January through April CS copies.

Dr. Howell informed Dr. Church that he is now in compliance with his Stipulation and Order for this quarter. She asked Dr. Church to update the Board regarding his work.

Dr. Church responded that he moved to Pleasant View, near Ogden. He stated that his pediatries practice has grown extremely fast. He stated that it was somewhat stressful to sell their home and move but feels that he has turned another corner in his recovery. Dr. Church stated that he listened to the prior probationer appointment and recalls being where that person is. He stated that he believed at one time that some of the requirements were not helpful to him and found reasons not to attend the recovery meetings, Dr. Church stated that the 12 step program is a critical component to recovery and there was something there for him to learn by attending and by attending the AA meetings. He stated that a person can have a positive or negative slant on attending the meetings. He stated that May 25, 2005 he went into recovery and never imagined at that time that he would be where he is today. He stated that at that time he believed his career was over and he lost a fellowship. He stated that he never thought he would be a pediatrician and he is so much happier in what he is now doing. Dr. Church stated that he is now in the process of becoming Board Certified.

Dr. Bennion asked Dr. Church how long he attended recovery meetings before they started to be worthwhile to him.

Dr. Church responded that it was about 6 months to a year. He stated that most of the people he knows who believe they get nothing out of the meetings are just attending to fill a requirement and are usually not working the 12 steps. He stated that a person has to be willing to take a chance to work the 12 steps. Dr. Church stated that the meetings are designed around how a person is living the 12 steps in their life. He stated that people differ spiritually but can still work the 12 steps successfully.

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Dr. Howell commented that it appears Dr. Church is feeling good in his recovery program. She stated that recovery has a lot to do with the patient's willingness to recover, accept and settle into the program. She stated that the Board has received positive reports. Dr. Howell asked Dr. Church if he craves the drugs when he writes prescriptions.

Dr. Church responded that relapse for him now is recognizing when he is feeling stressed and more wrapped up in himself and then removing himself from those things until he no longer even thinks of using drugs.

Dr. Church stated that he talked with Diana Baker and Ms. Taxin regarding requesting early termination from probation. He stated that he brought a letter from himself and will submit one from Dr. Allred when he returns to town.

Dr. Howell reviewed Dr. Church's file and noted that the Board decreased the frequency of meeting from quarterly to every 6 months at his last appointment. She asked Dr. Church when he was thinking he would like to have the probation terminated.

Dr. Church responded that Ms. Baker has said he should be at least ½ through the probation before requesting early termination. He stated that he is now at that half way mark and ready for termination. He stated that he has gleaned a real sense of gratitude and knows he will always participate in some form in the 12 step program, in the LDS program and in drug screening. He stated that the drug tests protect him from litigation and he would like a paper trail to show he has been sober. He stated that recovery has hills and valley and that the drug testing accountability helps him. Dr. Church stated that he believes he now has a strong support system in place.

Dr. Howell commented that Dr. Church's probation started January 24, 2006 for 5 years to January 24, 2011.

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Dr. Babitz recommended Dr. Church submit the following for review at the January 2009 Board meeting:

- 1. Submit a letter of request.
- 2. Submit letter of recommendation from the people who have treated him in 12 step, DayBreak, Bob Stevens in aftercare. He requested the letters address the progress Dr. Church has made.

Dr. Church responded that he will get the information for the Board to review. He stated that his Ohio probation goes through 2011. Dr. Church stated that his attorney has informed him that if Utah releases him early then Ohio may also consider early termination of the probation. He stated that the Ohio Board is less supporting and less encouraging than the Utah Board.

Ms. Harry reminded Dr. Church that his paperwork is still required quarterly.

Dr. Church asked if there is any reason that he would not be allowed to supervise a Physician Assistant at this time.

Ms. Taxin responded that the only restrictions on his license are outlined in his Stipulation and Order. She explained that he could only supervise 2 fulltime Physician Assistants.

The Board determined Dr. Church is in compliance with his Stipulation and Order.

An appointment was made for Dr. Church to meet again in January 2009.

11:15 am

Dr. Randal Ellsworth, Probationary Interview

Dr. Ellsworth met for his probationary interview.

Dr. Bennion conducted the interview.

Dr. Ellsworth informed the Board that he is at the Zion Center in St. George and works less than ½ time due his overall health. He stated that he no longer does surgery that may require long night hours. Dr.

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Ellsworth stated that the Board should have received a letter from Dr. Cohen. He commented that it feels good to do something useful after all his years of education. He informed the Board that his health condition is the same and, as long as he stays within his limits, he does ok

Dr. Bennion informed Dr. Ellsworth that the latest PIR and 12 step attendance cards have not been received.

Dr. Ellsworth submitted the cards. He stated that he met with Dr. Buckner, the Psychologist, yesterday and Dr. Buckner will submit a report.

Ms. Taxin commented that after the report has been received the Board may have some feedback for Dr. Ellsworth as Dr. Buckner is his therapist.

Dr. Ellsworth stated that Dr. Buckner has not worked with DOPL before and is looking for some guidance.

Ms. Taxin suggested Dr. Ellsworth have Dr. Buckner call her and she will review the expectations of the Division and the Board.

Dr. Bennion stated that Dr. Ellsworth did not call in for his drug testing on 2 days and missed a test one of those days. He asked Dr. Ellsworth to explain.

Dr. Ellsworth explained that he called and was tested today. He asked if he missed a test on Monday and what a missed test means.

Ms. Harry responded that he did miss a test on Monday and it means that his tests will be increased for two months. She stated that it is very important that he call in daily.

Ms. Taxin asked if there was a reason he failed to call.

Dr. Ellsworth responded that he forgot to call.

Dr. Babitz reminded Dr. Ellsworth that failing to

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call is considered a positive test.

Dr. Ellsworth responded he did not call when he went to Guatemala. He stated that he tried to get a hair test when he went to Germany and was informed that they could not do the hair test for about a week. He stated that he tried to explain that waiting a week would be too late but they would not accommodate him. He asked if he could do a hair test to make up missing the test on Monday.

Ms. Harry explained that Dr. Ellsworth was not required to do a hair test but was required to complete a regular test. Ms. Harry stated that he tested today and could not do a hair test for a make up test.

Dr. Bennion informed the Board that Dr. Ellsworth has paid the required fine. He then commented that Dr. Ellsworth voiced at the last meeting that he was not getting much out of attending the PIR meetings. He asked Dr. Ellsworth if he was of the same opinion today.

Dr. Ellsworth responded that he does not care for the rah, rah or the horror stories in the group meetings. He stated that the Provo group is smaller and a little better so he attends some meetings there. Dr. Ellsworth stated that he also attends an AA meeting in St. George. He stated that he is not an addict and he learned what he could while at Cirque Lodge for 30 days. He stated that he worked out some of the emotional issues he was having and did cross some boundaries which he handled wrong.

Dr. Howell responded that taking medications from others, splitting pills and operating under the influence is an addiction. She stated that the charges were pretty bad and he agreed with the Finding of Facts and signed the Stipulation and Order.

Dr. Ellsworth commented that he did not operate while under the influence. He stated that Soma makes him slur his speech but he did not do any surgery while taking Soma. Page 13 of 23 Minutes Physician's Board July 9, 2008

> Dr. Howell voiced concern that Dr. Ellsworth does not like attending AA meetings, he does not like the PIR meetings but he agreed to attend the meetings as part of his Stipulation and Order. She asked him what he would like to do.

> Dr. Ellsworth responded that he likes talking with Dr. Buckner. He stated that Dr. Buckner has identified some emotional problems and is helping him deal with them. He stated that he knows he did not do everything right but he does not find the principles of AA or PIR useful to him.

Dr. Howell asked if Dr. Ellsworth has tried the LDS 12 step program.

Dr. Ellsworth responded that he has and did not like attending there either. He stated that he read some scriptures and learned some things but he likes to read and study privately. He stated that he is attending AA meetings but they are not productive for him.

Dr. Howell stated that she believes the support groups are more productive to addicts. She stated that it will be challenging for him and if he does not like the AA groups then maybe attending the 12 step programs as there has to be at least 1 meeting type that is more tolerable for him.

Ms. Taxin commented that it is sad that he attends these meetings and they are a waste of time for him. She stated that the requirement is suppose to be a benefit for him. Ms. Taxin suggested Dr. Ellsworth ask his therapist if he knows of a program that would be more beneficial or a better fit and then let her know what the program is. She also suggested Dr. Ellsworth request his therapist to address the issue in therapy and in his next report.

The Board determined Dr. Ellsworth is out of compliance with his Stipulation and Order.

An appointment was made for Dr. Ellsworth to meet again on October 8, 2008.

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11:30 am

Dr. Brandon Bentz, Probationary Interview

Dr. Bentz met for his probationary interview.

Dr. James Pingree conducted the interview.

Dr. Bentz asked the Board if he could be released from therapy. He stated that he could always return to the therapist if necessary but that both the therapist and he believe he has gained the benefit to date and termination is appropriate. Dr. Bentz stated that his therapist is a person that he can talk openly with regarding any issues.

Dr. James Pingree responded that his request would be addressed later in the meeting. He stated that Dr. Bentz in compliance with his Stipulation and Order. He asked Dr. Bentz to update the Board.

Dr. Bentz responded that he has received funding to continue his research and will be up for tenure in October. He stated that he has taken this opportunity and experience to enrich his professional achievements and to work on his personal life. He stated that this has been an enriching experience but a blemish that he will earry for the rest of his career. Dr. Bentz stated that he has taken responsibility for his action and hopes to be able to put this behind him at some point in time. He then asked the Board if they would consider early termination of his probation.

Dr. James Pingree responded that Dr. Bentz probation is scheduled to be completed in August 2009. Dr. James Pingree stated that Dr. Bentz may formally request early termination in August and the Board will consider the request at that time.

Dr. Howell made a motion to terminate the therapy requirement. Dr. James Pingree seconded the motion. Dr. Howell, Dr. Fowler, Dr. Bennion, Dr. Ries, Dr. Sperry, Ms. Buhler, Dr. George Pingree, Dr. James Pingree and Dr. Howell vote in favor of the motion. Dr. Lamb abstained from voting. The motion passed with a majority vote.

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> Dr. Babitz asked Dr. Bentz to address the required chaperone issue, specifically anything that relates to his violation.

> Dr. Bentz responded that he has a separate Stipulation with the University regarding the chaperone. He stated that he is in compliance with the University stipulation and the chaperone report should have been received.

Dr. Babitz confirmed that the report was received.

The Board determined Dr. Bentz is in compliance with his Stipulation and Order.

An appointment was not made at this time as Dr. Bentz will try to get letters of recommendation and his request for early termination submitted in August or September. After the information has been received an appointment will be made.

12:00 pm to 1:00 pm

1:00 pm

Dr. Michael Goates, Probationary Interview

LUNCH

Dr. Goates and his legal counsel, Larry Keller, met for Dr. Goates probationary interview.

Dr. George Pingree conducted the interview.

Dr. George Pingree stated that all Dr. Goates drug tests for the last 4 months have been positive. He asked Dr. Goates to explain.

Mr. Keller responded that he has not been provided with the drug test information and he would contest.

Ms. Taxin explained to Mr. Keller that this meeting is not a hearing but a Board meeting that Dr. Goates is on probation and is expected to answer the Board's questions.

Mr. Keller responded that if the questions being asked relate to the issues regarding the Order to Show Cause (OSC) then he would contend that the information should not be discussed here.

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Dr. Howell reiterated that this is a Board meeting and not an OSC hearing.

Dr. Babitz again stated that the drug testing company has reported that 18 of the last 19 tests Dr. Goates has had were positive tests. He stated that the Board would still like Dr. Goates to explain.

Mr. Keller responded that since Dr. Goates will be responded at a hearing then he will not respond at this time

Dr. Babitz commented that Dr. Goates has the right to respond or not to respond at this time.

Dr. George Pingree then asked Dr. Goates how he is doing.

Dr. Goates responded that it has been difficult to receive payments as the insurance companies will no longer reimburse him.

Dr. George Pingree asked Dr. Goafes when he last drank alcohol.

Dr. Goates responded that he does not remember that far back

Dr. George Pingree stated that Dr. Brunson reported that Dr. Goates has denied any alcohol consumption.

Dr. Goates responded that he sees Dr. Brunson every Thursday.

Dr. Babitz stated that there are numerous people taking the drug tests and all of them have had negative tests. He suggested that Dr. Goates not use anything that would cause a false positive or a true positive. He stated that he is wondering why Dr. Goates has not changed his habits and is not doing everything and anything so that the tests are not a false positive or a true positive.

Dr. Goates responded that several months ago he

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informed the Board that he was under the care of a Dentist for a gingivitis problem and that if he does not use the mouthwash he will lose his teeth.

Dr. Babitz asked if Dr. Goates is suggesting that the mouthwash he uses is causing the high levels of positive tests that have been reported.

Dr. Goates responded that there is alcohol in bar-b-que sauce, vinegar, mouthwash, hand wash and many other everyday items.

Dr. Babitz commented that if that is the case, why would be continue to use those items?

Dr. Howell stated that the Board has not seen any documentation regarding Dr. Goates would loose his teeth if he does not use this monthwash.

Mr. Keller responded that he will present information at the hearing regarding the use of the mouthwash. He asked the Board not to judge until after the hearing.

Dr. Howell stated that alcohol is something that shows up positive on a test and there is no medical documentation or evidence substantiating Dr. Goates using the specific mouthwash or that it is required. She stated that Dr. Goates should understand the Board's concern that the mouthwash use might be just a smoke screen.

Ms. Taxin stated that she asked Dr. Goates to talk to his Dentist regarding another mouthwash that does not have alcohol and to submit documentation to her. She stated that she has not yet received any documentation. Ms. Taxin stated that Dr. Goates submitted a picture of the bottle with no explanation regarding why he needed it.

Dr. Goates responded that he takes 4 ounces twice a day, swishes his mouth and then expels and does not swallow.

Dr. Bennion asked how long Dr. Goates has been using the mouthwash.

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Dr. Goates responded that he has used the mouthwash about 5 years.

Dr. Sperry asked if Dr. Goates has discussed with his Dentist regarding other treatments or alternatives.

Dr. Goates responded that he talked with his Dentist a few weeks ago and the Dentist informed him that this was the only treatment. He stated that he believes he is in compliance with his Stipulation and Order as all his reports have been submitted.

Ms. Taxin stated that Dr. Goates is compliant with his reports. She stated that he is out of compliance with his Stipulation and Order based on the positive drug tests. She stated that all others issues may be addressed at the hearing.

Dr. Ries commented that 4 ounces seems like a lot of liquid at one time.

Dr. Goates responded that he is required to swish for a specific number of seconds and then to spit out the mouthwash. He then informed the Board that he will going on vacation August 4, 2008 through August 10, 2008. He stated that he will be hiking in the Deadwood, South Dakota area where they hike several days into a cabin and then hike out and won't be near a testing center. Dr. Goates requested the Board to waive the drug testing during that period of time.

Dr. Lamb made a motion to exempt Dr. Goates from drug testing from August 4, 2008 through August 10, 2008. Dr. Bennion, Dr. Fowler, Ms. Buhler, Dr. Howell, Dr. George Pingree, Dr. James Pingree, and Ms. Buhler voted in favor. Dr. Ries and Dr. Sperry opposed the motion. Dr. Babitz abstained from voting. The motion passed with a majority vote.

Ms. Taxin informed Dr. Goates that Ms. Harry would contact him.

The Board determined Dr. Goates is out of compliance with his Stipulation and Order.

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1:15 pm to 1:45 pm Dr. Richard Melling, MD, Utah Biopharmaceutical Laboratories No appointment was made at this time due to the scheduled hearing.

Dr. Melling and Doug McClain met with the Board to discuss their application for a Pharmacy license.

Ms. Taxin explained that Dr. Melling submitted an application for a Manufacturing Pharmacy license. She explained that Dr. Melling's company uses processed goat serum to help MS patients and other types of autoimmune diseases. She explained that the company does not currently have an FDA number and approval to produce the product for human use and she therefore would have had to deny their application. She stated that she allowed Dr. Melling to withdraw his application but he requested to meet with the Board to explain what he what he wants to do at Utah Biopharmaceutical Laboratories.

Dr. Melling explained that he treats MS patients in Beaver, Utah. He stated that Beaver area has the highest MS numbers in the world. Dr. Melling explained that Dr. Erickson, in Texas, was using this medication with a Texas waiver and there is a Dr. Morales in Mexico that distributes 3 month supplies of the medication to U.S. citizens who were going there to obtain the medication and bringing it back to the U.S. He explained that he facilitated some patients receiving the medication from Mexico. Dr. Melling stated that Gary Herbert, the Lt. Governor of Utah, has stated that if there was a Utah company manufacturing and distributing the medication prior to FDA approval it would be a great thing for the State. He then explained the manufacturing process. Dr. Melling stated that his application would have been denied based on the lack of FDA registration so he requested the application be withdrawn. He explained that his attorneys have stated that he does not need the FDA registration and he is waiting to see what determination the Division attorneys will make. He stated that his goal is to treat his patients who have MS and have failed in the traditional therapy for the disease.

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Mr. McClain stated that the testing is in Phase I right now.

Dr. Melling stated that they anticipate moving into Phase II after they receive Orphan designation. He stated that the product is now being manufactured in Texas by Iso-Tex and he has a letter from Iso-Tex that they have the approval of Texas to manufacture. He stated that currently the product is being manufactured in Boston, is sent to Wales and then to Texas. He stated that if the Board would approve the product it would be manufactured in Boston, sent to Wales and then directly to him for his patients.

Ms. Taxin stated that she was informed that the facility in Texas is a nuclear facility. She asked if Dr. Melling has any documentation regarding the type of facility that is in Texas.

Dr. Melling responded that he does have the documentation regarding the type of facility that is in Texas.

Mr. McClain commented that they are now in the process of obtaining the FDA approval.

Dr. Melling stated that there are many medicines used that are not FDA approved. He stated that he is asking the Physician's Board for a waiver. He stated that he receives many phone calls each week requesting information on obtaining the medication. Dr. Melling stated that he refers patients to Dr. Morales in Mexico.

Ms. Taxin asked Dr. Melling how he knows the medication given out by Dr. Morales is what it is proposed to be.

Dr. Melling responded that he does not know if it is what it is suppose to be but it works. He stated that the medication arrives in unlabeled bottles, it is expensive and there is no return policy so patients use the medication. He stated that he has called several times for guidance.

Ms. Taxin informed the Board that the Pharmacy

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> Board did not believe the Division made an error in their decision not to license Dr. Melling as he does not meet requirements for a Manufacturing Pharmacy.

> Dr. Babitz commented that if Dr. Melling is planning to manufacture and dispense then he is on slippery slope as the Physician's Law will not allow for him to do both. He stated that Physicians administer, furnish and prescribe only and the Pharmacy includes storage, pill counting, manufacturing, dispensing to the patient to take at home. He stated that the first principal of a Physician is to do no harm and without FDA approval he is not sure if the product could or would do harm. He stated that Dr. Melling would be meeting with the Board for a different reason if a patient alleged they were harmed.

Dr. Melling explained that Iso-Tex was given a compassionate waiver but it is not on Orphan status yet. He stated that he believes he is following the practice as it is written in the Laws and Rules. Dr. Melling then asked to discuss alternative practices as a way he can use this medicine.

Ms. Taxin stated it is her understanding that if Dr. Melling is able to get the drug declared as an alternative drug then it won't get FDA approval.

DISCUSSION ITEMS:

Review Dr. Stanton Bailey's Request for Early Termination of Probation The Board reviewed Dr. Bailey's request for early termination of probation. The Board requested Dr. Bailey submit a second evaluation that supports the earlier evaluation.

FYI

Ms. Taxin informed the Board that Dr. Paul Ray Taylor surrendered his license. **No Board action was taken.**

FYI

The Board noted the Order to Show Cause Hearing on August 13, 2008 at 1:00 pm.

Board members asked how action was taken so quickly on this case while other cases take a long time.

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Ms. Taxin responded that if there are concerns on other cases to notify her and she will check on them.

Ms. Taxin informed the Board that Michael Pope is a new probationer that will be meeting with them. She stated that he has been on top of his requirements and notified her that he had a trip planned. She stated that Dr. Pope asked if the AMA free CE would count toward his requirement.

Dr. Howell responded that if the CE is a category 1 then it would count.

Ms. Taxin stated that she watched videos regarding the USMLE and SPEX examinations. She stated that the videos are about 20 minutes and talk about the process and how to prepare. Ms. Taxin asked if the Board would be interested in the information.

Dr. Babitz informed the Board of a training program. He stated that after the clinical skills there is a Step 2 to use the practical skills of going around to patients, spend time with them, ask them questions, evaluate them and then go out of the room and write up the evaluation. He stated that it is a good program.

Ms. Taxin stated that she attended the CPEP training program and it was another informative program for reentry or probationers.

Board members asked Ms. Taxin to show the videos of the examination information that she has in her office.

CORRESPONDENCE:

FSMB BoardNet News

The Board reviewed the FSMB BoardNet News. No Board action was taken.

FSMB State of the States Physician Regulation 2008 Pamphlet

The Board reviewed the FSMB State of the States Physician Regulation 2008 Pamphlet. **No Board action was taken.**

FYI

TYI - Examinations

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Utah Medical Association Bulletin, June-July

2008

The Board reviewed the Utah Medical Association Bulletin, June-July 2008. No Board action was

taken.

NBME Examiner, Spring/Summer 2008 The Board reviewed the NBME Examiner.

Spring/Summer 2008. No Board action was taken.

E-mail to Ms. Taxin Ms. Taxin reviewed the e-mail regarding CME in

Chicago. No Board action was taken.

2009 Annual Meeting Ms. Taxin informed the Board that March 30, 2009

through April 2, 2009 is the schedule for the annual meeting. She asked if any Board member would be interested in attending. She stated that she is planning

to attend the meeting.

Dr. Babitz and Dr. George Pingree voiced a desire

to attend.

NEXT MEETING SCHEDULED FOR: August 13, 2008

ADJOURN: Motion to adjourn by Dr. Bennion, Dr. Howell

seconded the motion.

The time is 2:15 pm and the Board meeting is

adjourned.

Note: These minutes are not intended to be a verbatim transcript but are intended to record the significant features of the business conducted in this meeting. Discussed items are not necessarily shown in the chronological order they occurred.

August 13, 2008 (ss) Marc E. Babitz, MD

Date Approved Chairperson, Utah Physician's Licensing Board

<u>July 28, 2008</u> (ss) Noel Taxin

Date Approved Bureau Manager, Division of Occupational &

Professional Licensing